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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,175	07/11/2001	Hau H. Doung	A-68718-3/RFT/RMS/RMK	1169

7590 09/25/2006

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,175	DOUNG ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-52 and 54-66* is/are pending in the application.

4a) Of the above claim(s) *65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-52,54-64 and 66* is/are rejected.

7)☒ Claim(s) *55 and 60* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 17 July 2006 in which claims 42, 45, 49 and 65 were amended. the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 15 March 2006 are withdrawn in view of the amendments. The previous objections are maintained.

Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejection and new grounds for rejection. New grounds for rejection, necessitated by amendment, are discussed.

Claim 65 is withdrawn from consideration.

Claims 42-52, 53-64 and 66 are under prosecution.

Claim Objections

2. The following objections are reiterated from the previous office action. Applicant has not responded to the objections or made the required corrections.

3. Claims 55 and 60 are objected to because of the following informalities:

Claim 55 is objected to because it does not further limit Claim 42.

Claim 60 is objected to because it contradicts the nucleic acid binding ligands of Claims 42, 45 and 49.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 42-47, 52, 54-57, 60-64 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter et al (U.S. Patent No. 6,207,369, filed 17 September 1996) in view of Goldberg et al (U.S. Patent No. 5,959,098 issued 28 September 1998).

Regarding Claim 42, Wohlstadter et al disclose a cartridge comprising a reaction chamber having an array of electrodes on a substrate (Column 8, lines 38-44), the substrate having a SAM layer (Column 22, lines 34-44) and nucleic acid probe covalently attached (Column 39, lines 20-28), the cartridge further comprising an inlet and outlet port (Column 43, lines 46-55) and electrical connections for the electrodes (Column 85, lines 1-12). Wohlstadter et al teach the cartridge having inlet and outlet ports. Wohlstadter et al are silent regarding minimizing introduction or retention of bubbles via positions of the inlet and outlet port. However, configuration of reaction chambers so as to minimize retention of bubbles within the chamber was well known in the art at the time the claimed invention was made as taught by Goldberg et al.

Goldberg specifically teaches that bubbles in a reaction chamber are problematic in that bubbles may prevent complete exposure of the substrate to a reaction fluid (Column 16, lines 36-39). To minimize the retention of bubbles, Goldberg et al teaches a preferred reaction chamber comprising ports wherein outlet port and inlet port are positioned at the highest and lowest positions respectively so as to facilitate removal of unwanted bubbles from the chamber (Column 16, lines 16-21). It would have been obvious to one of ordinary skill in the art at the

time the claimed invention was made to apply the chamber configuration of Goldberg et al to the reaction chamber of Wohlstadter et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of facilitate removal of problematic bubbles from the chamber as taught by Goldberg et al (Column 16, lines 16-21).

Regarding Claim 43, Wohlstadter et al disclose the cartridge wherein the ports are separated (Column 43, lines 44-67 and Fig. 69). And Goldberg et al teach the probes are separated (Column 16, lines 16-21).

Regarding Claim 44, Wohlstadter et al disclose the cartridge wherein the ports are connected via the cartridge (Column 43, lines 44-67).

Regarding Claim 45, Wohlstadter et al disclose a cartridge comprising a reaction chamber having an array of electrodes (Column 8, lines 38-44) wherein the electrodes are a printed circuit on the substrate (Column 85, lines 7-12), the substrate having a SAM layer (Column 22, lines 34-44) and nucleic acid probe covalently attached (Column 39, lines 20-28), the cartridge further comprising an inlet and outlet port (Column 43, lines 46-55) and electrical connections for the electrodes (Column 85, lines 1-12). Wohlstadter et al are silent regarding minimizing introduction or retention of bubbles via positions of the inlet and outlet port. However, configuration of reaction chambers so as to minimize retention of bubbles within the chamber was well known in the art at the time the claimed invention was made as taught by Goldberg et al.

Goldberg specifically teaches that bubbles in a reaction chamber are problematic in that bubbles may prevent complete exposure of the substrate to a reaction fluid (Column 16, lines 36-39). To minimize the retention of bubbles, Goldberg et al teaches a preferred reaction chamber comprising ports wherein outlet port and inlet port are positioned at the highest and lowest positions respectively so as to facilitate removal of unwanted bubbles from the chamber (Column 16, lines 16-21). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the chamber configuration of Goldberg et al to

the reaction chamber of Wohlstadter et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of facilitate removal of problematic bubbles from the chamber as taught by Goldberg et al (Column 16, lines 16-21).

Regarding Claim 46, Wohlstadter et al disclose a cartridge wherein the electrodes are a printed circuit on the surface of the substrate (Column 85, lines 7-12).

Regarding Claim 47, Wohlstadter et al disclose a cartridge wherein the electrodes are a fabricated (i.e. screen printed) on the surface of the substrate (Column 85, lines 7-12).

Regarding Claim 52, Wohlstadter et al disclose the cartridge of Claim 42 wherein the electrodes are a printed circuit on the substrate (Column 85, lines 7-12).

Regarding Claim 54, Wohlstadter et al disclose the cartridge having a gasket (Column 103, lines 41-46).

Regarding Claim 55, Wohlstadter et al are silent regarding an outlet. However, Goldberg et al teach the reaction chamber wherein the outlet facilitates bubble removal (Column 16, lines 13-212).

Regarding Claim 56, Wohlstadter et al disclose the cartridge wherein the array is on a one surface of the substrate (Fig. 5-6) and Goldberg et al disclose the substrate wherein an array is on one surface i.e. substrate wafer (Column 29, lines 7-12)

Regarding Claim 57, Wohlstadter et al disclose the cartridge wherein the array is on a one surface of the substrate (Fig. 5-6) but Goldberg et al disclose the substrate further having two surfaces wherein each comprises an array i.e. substrate wafer having a grid pattern wherein each grid is a surface having an array (Column 29, lines 7-12).

Regarding Claim 60, because the claim is drawn to a capture binding ligand of Claims 42, 45 and 49 and because the ligand is not a component of the devices of Claims 42, 45 and 49, Claim 60 does not further limit the devices of Claims 42, 45 and 49.

Regarding Claim 61, Wohlstadter et al disclose the cartridge further comprising a assay complex comprising a capture probe, a target and an electron transfer moiety (Column 21, line

37-Column 22, line 45) where the transfer moiety is an ECL tagged complex to which electrons are transferred from the electrode via the chemical reaction (Column 4, line 39-Column 5, line 34).

Regarding Claim 62, Wohlstadter et al disclose the cartridge wherein the self-assembled monolayer comprises a conductive oligomer i.e. linking chain to efficiently transport electrons (Column 39, lines 60-62).

Regarding Claim 63, Wohlstadter et al disclose the cartridge wherein the electrodes are gold (Column 85, lines 7-12).

Regarding Claim 64, Wohlstadter et al disclose the cartridge wherein the self assembled monolayer comprises a thio-containing monolayer forming species (Column 11, lines 16-20).

Regarding Claim 66, Wohlstadter et al disclose the cartridge wherein the nucleic acid is linked via a conductive oligomer i.e. linking chain to efficiently transport electrons (Column 39, lines 60-62).

6. Claims 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter et al (U.S. Patent No. 6,207,369, filed 17 September 1996) in view of Goldberg et al (U.S. Patent No. 5,959,098 issued 28 September 1998) as applied to Claims 42, 45 and further in view of Lipshutz et al (U.S. Patent No. 6,043,080, issued 28 march 2000).

Regarding Claim 48-51, Wohlstadter et al disclose a cartridge comprising a reaction chamber having an array of electrodes on a substrate (Column 8, lines 38-44), the substrate having a SAM layer (Column 22, lines 34-44) and nucleic acid probe covalently attached (Column 39, lines 20-28), the cartridge further comprising an inlet and outlet port (Column 43, lines 46-55) and electrical connections for the electrodes (Column 85, lines 1-12). Wohlstadter et al and Goldberg teach the cartridge having inlet and outlet ports but are silent regarding the

inlets having membranes or filters. However, reaction cartridges having membranes were well known and routinely practiced in the art at the time the claimed invention was made as taught by Lipshutz et al.

Specifically, Lipshutz et al teach a reaction cartridge comprising membranes positioned at an inlet to remove any debris and/or proteins from the sample prior to entering the reaction chamber. Lipshutz et al further teach the membrane is semi-permeable (i.e. fluid permeable, debris impermeable) wherein any well known membrane material would be useful in the device (Column 30, lines 10-23). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the membrane of Lipshutz et al to the reaction chamber of Wohlstadter et al and/or Goldberg et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of removing debris and/or proteins from the sample prior to entering the reaction chamber as desired in the art (Lipshutz et al, Columns 30, lines 10-23).

7. Claims 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter et al (U.S. Patent No. 6,207,369, filed 17 September 1996) in view of Goldberg et al (U.S. Patent No. 5,959,098 issued 28 September 1998) as applied to Claims 42, 45 and 49 above and further in view of Hayes et al (U.S. Patent No. 6,334,980, filed 25 September 1998).

Regarding Claims 58-59, Wohlstadter et al disclose a cartridge comprising a reaction chamber having an array of electrodes on a substrate (Column 8, lines 38-44), the substrate having a SAM layer (Column 22, lines 34-44) and nucleic acid probe covalently attached (Column 39, lines 20-28), the cartridge further comprising an inlet and outlet port (Column 43, lines 46-55) and electrical connections for the electrodes (Column 85, lines 1-12). Wohlstadter

et al teach the cartridge having inlet and outlet ports. Wohlstadter et al and Goldberg discuss reagent reservoirs but are silent regarding the reservoirs positioned in a removable cover.

However, reaction chambers having removable covers and containing reagent reservoirs were well known in the art at the time the claimed invention was made as taught by Hayes et al.

Hayes et al teaches a self-contained and portable reaction chamber comprising reservoirs in a removable cover (#70-72). Hayes teaches that the self-contained chamber comprises reagents preloaded in the reservoirs so as to reduce the complexity of steps that must be performed on site (Column 3, lines 25-30). Hayes also teaches that the removable cover permits addition of test samples to the chamber at desired times e.g. later/on site (Column 12, lines 44-49). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the reaction chamber of Wohlstadter et al by providing the pre-loaded reservoirs and removable cover as taught by Hayes et al for the expected benefit of providing a self-contained and portable device on site use while permitting addition of the sample on site as desired in the art Hayes et al (Column 3, lines 25-30 and Column 12, lines 44-49).

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 42-52, 54-64 and 66 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,761,816 in view of Goldberg et al (U.S. Patent No. 5,959,098, issued 28 September 1999). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to very similar cartridges comprising a substrate with an electrode array, SAM and covalently attached nucleic acids and electrical connections. The claims sets merely differ in the arrangement of limitations within the claim set e.g. independent claims of the instant claim set define the capture ligand as a nucleic acid while dependent claim 13 so defines the ligand. The claim sets further differ in that the instant claims define the cartridge has having inlet and/or outlet ports. However, cartridges having ports were well known and routinely practiced in the art at the time the claimed invention was made as taught by Goldberg et al who teach that bubbles in a reaction chamber are problematic in that bubbles may prevent complete exposure of the substrate to a reaction fluid (Column 16, lines 36-39). To minimize the retention of bubbles, Goldberg et al teaches a preferred reaction chamber comprising ports wherein outlet port and inlet port are positioned at the highest and lowest positions respectively so as to facilitate removal of unwanted bubbles from the chamber (Column 16, lines 16-21). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the chamber configuration of Goldberg et al to the reaction chamber of '816. One of ordinary skill in the art would have been motivated to do so for the expected benefit of facilitate removal of problematic bubbles from the chamber as taught by Goldberg et al (Column 16, lines 16-21).

10. Claims 42-52, 54-64 and 66 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 10-12, 14-16, 32-34 of allowed Application No. 09/712,792. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to very similar cartridges comprising a substrate with an electrode array, SAM and covalently attached nucleic acids and electrical connections. The claims sets merely differ in the arrangement of limitations within the claim sets and terminology used to describe elements of the cartridge. For example, independent claims of the instant claim set define the capture ligand as a nucleic acid while dependent claim 12 so defines the ligand. Further, instant claims define the chamber as having a port while the '792 claim sets define a channel, both the channel and port are defined by a filter membrane. Therefore, the claims sets are drawn to cartridges that are not patentably distinct.

11. Claims 42-52, 54-64 and 66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-24 of copending Application No. 10/412,660. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to very similar cartridges comprising a substrate with an electrode array, SAM and covalently attached nucleic acids and electrical connections. The claims sets merely differ in the arrangement of limitations within the claim sets e.g. independent claims of the instant claim set define the capture ligand as a nucleic acid and the substrate as having an array of electrodes while dependent claims 21 & 23 of the '660 application so define the invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
September 14, 2006